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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,273	08/27/2001	Gust H. Bardy	032580.0027.UTL	5279

21691 7590 01/13/2005

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EXAMINER	
MULLEN, KRISTEN DROESCH	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/940,273	BARDY ET AL.
	Examiner	Art Unit
	Kristen Mullen	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/8/04 (Response)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-219* is/are pending in the application.

4a) Of the above claim(s) *1-52 and 137-219* is/are withdrawn from consideration.

5)☒ Claim(s) *76* is/are allowed.

6)☒ Claim(s) *53-75,77-116 and 119-136* is/are rejected.

7)☒ Claim(s) *117 and 118* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The indicated allowability of claims 57-75, and 77-94 are withdrawn in view of the newly discovered reference(s) to Hauser (5,385,574). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 53-54, 63, 70-72, 74-75, 77, 84-90, 95-96, 105, 112-114, 116,119, and 126-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (5,385,574).

Regarding claim 53, Hauser et al shows an implantable cardioverter-defibrillator comprising: a housing; an electrical circuit located within the housing; a first electrode (14, 14' 70, 62, 64, 66; 28, 29) coupled to the electrical circuit, wherein the first electrode is positioned at a first point with respect to the patient's heart; and a second electrode (28, 29; 14, 14' 70, 62, 64, 66) coupled to the electrical circuit, wherein the second electrode is positioned at a second point that is substantially on the opposite side of the patient's heart from the first point (Fig. 6).

"Subcutaneous" has been interpreted to mean under the skin.

With respect to claims 54, 72, 96, and 114, Hauser et al shows at least a portion of the housing or electrode is curved (edges) (Fig. 7).

Regarding claims 63, and 105, Hauser et al further shows the first electrode (62, 64, 66) can emit energy for shocking a patient's heart.

With respect to claims 70-71, and 112-113, Hauser et al. further shows the first electrode can further receive sensory information (Col.7, lines 9-15).

Regarding claims 74, and 116, Hauser et al further shows at least a portion of the housing surrounding the electrode is ceramic. (Col. 6, lines 52-60).

With respect to claim 75, Hauser et al. shows the second electrode (14, 14' 70, 62, 64, 66) is located on the housing.

Regarding claim 77, Hauser et al further shows the second electrode (28, 29) is disposed on a lead.

With respect to claim 95, Hauser et al. shows an implantable cardioverter- defibrillator comprising a housing an electrical circuit located within the housing, a first subcutaneous electrode located on the housing (14, 14' 70, 62, 64, 66) and coupled to the electrical circuit; and a second subcutaneous electrode (28, 29) coupled to the electrical circuit, wherein the second electrode is spaced from the first electrode by a length and wherein a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes.

Regarding claim 119, Hauser et al further shows the second electrode (28, 29) is disposed on a lead.

The functional language and statements of intended use (such that etc., adapted to) have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 55-58, 73, 78-83, 91-94, 97-100, 115, 120-125, 132-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574). Hauser et al. discloses the claimed invention except for the specific dimensions of the housing and first electrode, and the length of the lead. It would have been an obvious matter of design choice to size the length of the canister between approximately 3 cm to 30 cm long, approximately 5 cm to 20 cm long, or approximately 5 cm to 12 cm long; the depth of the canister to be less than 15 mm; a portion of the first electrode is curved; and the area of the first electrode to be less than 1000 mm^2 or 2000 mm^2; the length of the lead to be approximately 5 cm to 55 cm, approximately 5 cm to 15 cm, approximately 15 cm to 25 cm, approximately 25 cm to 35 cm, approximately 35 cm to 45 cm, approximately 45 cm to 55 cm; the degree of separation between the first electrode and the second electrode with respect to the heart to be between approximately 30 and 90 degrees, approximately 90 and 120 degrees, approximately 120 and 150 degrees, and approximately 150 and 180 degrees since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

6. Claims 59-62, 101-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) in view of Mouchawar (5,601,608). Hauser et al. discloses the claimed

invention except for setting forth the specific waveforms utilized for defibrillation. Mouchawar teaches that monophasic and biphasic (multiphasic) defibrillation waveforms are well known (Figs. 5, 7, Col. 7, lines 12-58). Mouchawar also teaches that using a tri-phasic (multiphasic) charge balanced defibrillation waveform reduces post-shock block, and it was determined experimentally that the defibrillation threshold using a tri-phasic charge balanced defibrillation waveform was superior to the defibrillation threshold using conventional and charge balanced biphasic shocks (Col. 10, lines 45-67; Col. 11, lines 16-67). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hauser et al. to include the well known monophasic or biphasic (multiphasic) defibrillation waveforms or the advantageous triphasic (multiphasic) charge balanced defibrillation waveform of Mouchawar in order to utilize well known defibrillation waveforms or to reduce post-shock block and utilize a waveform having a lower defibrillation threshold than conventional and charge balanced biphasic shocks.

7. Claims 64-69, and 106-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) and further in view of Ostroff (5,215,081). Hauser et al. is as explained before. Although Hauser et al. fails to specify the desirable shock energy for shocking the patient's heart, attention is directed to Ostroff who teaches that the cardioversion-defibrillation energy is directly related to capacitance, shock duration, voltage, and resistance of the electrodes which in turn is dependent on electrode position and integrity (Col. 5, lines 50-56). It would have obvious to one with ordinary skill in the art at the time the invention was made to utilize the ranges of shock energies set forth in the claims, since it is well known in the art that

these factors are related to one another, and the ultimate energy delivered to the heart is dependent on these factors along with the resistance measured between the electrodes.

Response to Arguments

8. Applicant's arguments with respect to claims 95-116- and 119-136 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

9. Claim 76 is allowed.

10. Claims 117-118 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With respect to claim 117, the prior art of record fails to teach or suggest an implantable cardioverter-defibrillator comprising a housing; a first subcutaneous electrode and a second subcutaneous electrode coupled to an electrical circuit located within the housing, wherein the second electrode is spaced from the first electrode by a length and wherein a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes all in combination with the first and second subcutaneous electrodes being located on the housing.

Regarding claim 118, the prior art of record fails to teach or suggest an implantable cardioverter-defibrillator comprising a housing; a first subcutaneous electrode and a second subcutaneous electrode coupled to an electrical circuit located within the housing, wherein the second electrode is spaced from the first electrode by a length and wherein a cardioversion-defibrillation energy is delivered between the first and the second subcutaneous electrodes all in combination with the housing having a fist end and a second end and the first electrode being

located on the first end of the housing and the second electrode being located on the second end of the housing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Mullen

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